

#### REMARKS

Claims 1-55 are pending. Claims 1-55 stand variously rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 5,456,692), in view of Nappholz-I (US 5,720,770), Cox (US 5,383,912), and Nappholz-II (US 5,690,690) as further exemplified by Robson (US 5,231,987), and additional cited references.

Applicants previously argued that none of the cited references include at least the following limitation of claim 1:

a universal communication module comprising means for at least one of updating and reprogramming at least portions of the software loaded in the IMD, the communication module being configured to operate in conjunction with a plurality of different commercially available implantable medical devices originating from different manufacturers and being selectively programmable to communicate with, receive data from, and download data to any of various implantable medical devices.

Further, Applicants argued that none of the art includes at least the following limitation of claim 29:

at least one of a mobile telephone and a PDA, the at least one of the mobile telephone and the PDA further comprising means for at least one of updating and reprogramming at least portions of the software loaded in the IMD, the at least one of the mobile telephone and the PDA being capable of simultaneously receiving information from and relaying information to the IMD, wherein the updating and programming means is a universal device configured to operate in conjunction with a plurality of different commercially available implantable medical devices originating from different manufacturers and being selectively programmable to

communicate with, receive data from, and download data to any of various implantable medical devices;

The above-referenced office action responds to Applicants arguments by lodging a new basis for the rejection and contending that the alleged novelty of a universal communications module configured to operate in conjunction with a plurality of different commercially implantable medical devices originating from different manufactures and being selectively programmable to communicate with, receive data from, and download data to any of various implantable medical devices is known from Nappholz-II as exemplified by Robson. The teaching in Nappholz-II is of a universal programmer for reprogramming various models of only cardiac pacemaker devices, wherein the different models refers to different devices of the same manufacturer (see Table I) which are each operable in a different mode (see Table II).

Claims 1 and 29 further specify that the universal communications module is configured to operate in conjunction with a plurality of different commercially available implantable medical devices originating from different manufacturers. The Examiner has stated that Robson teaches a module being configured to operate in conjunction with a plurality of different commercially available implantable devices from different manufacturers. Robson discloses a device for testing the integrity of implantable electrodes. An application specific integrated circuit is used to package a time-domain reflectometer (TDR) in an implantable multi-programmable pacemaker for testing the integrity of an implanted electrode connected to the pacemaker (col. 5, lines 14-20). A programmer used to program the pacemaker includes a database of electrode manufacturers and models (col. 7, lines 21-24), allowing a physician to select the electrode to be implanted and connected to the pacemaker (col. 7, line 35-39). Industry standards provide specifications for medical lead connector assemblies allowing

medical leads from one manufacturer to be used with a pacemaker from another manufacturer. The device disclosed by Robson merely allows a physician to use a programmer to select the manufacturer and model of an electrode connected to the pacemaker. The programmer is being used to program a given pacemaker, and Robson makes no suggestion that the programmer is configured to operate in conjunction with a plurality of different commercially available pacemakers originating from different manufacturers. While an implanted electrode may be referred to as an implantable medical device (IMD) and the programmer as taught by Robson is used in conjunction with electrodes from different manufacturers, the electrode does not meet the requirements of an IMD according to the properly construed claims. As stated in claims 1 and 29, an IMD is specified as "being capable of simultaneous bi-directional communication with a communication module" and "comprising a memory having software loaded therein and means for permitting the software to be at least one of updated and reprogrammed after the IMD has been implanted". An implanted electrode, in and of itself, is not capable of simultaneous bi-directional communication and does not include a memory having software loaded therein that can be updated and reprogrammed as required by the properly construed claims.

As such, Robson fails to teach or suggest a universal communication module being configured to operate in conjunction with a plurality of different commercially available IMDs originating from different manufacturers, given a proper meaning of "IMD" in the context of the claims and the specification. Simply coupling any electrode from any manufacturer to a pacemaker and using a programmer to program the pacemaker does not make the programmer a universal programmer and is not an appropriate reading. None of the additionally cited references remedy this deficiency. Accordingly, Applicants submit that claims 1 and 29, as well as the dependent claims, distinguish over the combination of references cited. Even when combined, the cited references fail

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to meet the claims. Applicants respectfully submit that the rejection is improper and should be withdrawn.

Applicants respectfully request that a notice of allowance be issued in due course so that the claimed invention may pass to timely issuance as U.S. Letters Patent. The Examiner is invited to contact the undersigned with any questions regarding this Response.

Respectfully submitted,

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